REMARKS

In view of the following Remarks, the Examiner is requested to withdraw the rejection and allow Claims 1-8, 13-16, and 81-83, the only claims pending and currently under examination in this application.

FORMAL MATTERS:

Claims 9-12 are canceled without prejudice.

Claims 1, 13, 14 and 82 are amended. Claim 13 is amended to clarify antecedence. Claims 1, 14 and 82 are amended to incorporate the elements of Claim 12 as originally filed. Claims 1, 14 and 82 are amended to clarify claim language so as to overcome objections raised by the Examiner by telephone interview, and thus are entered solely for the purpose of placing the claims in condition for allowance. Support for these amendments is found at for example page 3, lines 18-22 and page 17, lines 10-17.

No new matter is added. As such, the Examiner is requested to enter the above amendments.

INTERVIEW SUMMARY:

Applicants thank Examiner Harris for the courtesy of conducting telephonic interviews on July 15 and 16, 2009 with Applicant's representative Elizabeth Alcamo to discuss the rejections in the Final Office Action. Applicants discussed the differences between the cited art and the claimed invention, and presented arguments on how the claims as presented in the response filed March 2, 2009 reflect these differences. Examiner Harris indicated that these differences would not be considered as part of the method because they constituted a mental step rather than an active step, and that the addition of active steps would, in the Examiner's opinion, be required to clarify the intent of the Applicant and overcome the 35 USC § 102(b) and 103 rejections.

REJECTIONS UNDER §102

I. Claims 1, 2, 4-7, 9-15, 82 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Ricci et al. (Am. J. Respir. Cell. Mol. Biol. 25:439-446, 2001).

In making this rejection, the Examiner asserts that "Ricci discloses a method of assaying for the presence of neurotrophic tyrosine kinase receptor type 2 (NTRK2/TrkB), as well as other proteins associated with cellular locomotion in membranes from human bronchioalveolar carcinoma, adenocarcinoma, squamous cell carcinoma and small cell lung cancer using cytoplasmic immunostaining." (p. 4, l. 6-10) In addition, the Examiner asserts that "Applicants' claims recite a step of "using" and newly cited wherein clause, which are not given patentable weight because it simply expresses the intended result of the process step positively recited in the 'assaying' step, see MPEP 2111.01 [R-3]." (p. 3, l. 27-p. 4, l. 1) Further to this point, the Examiner asserts that "'Using said result' does not appear to materially differentiate or impart any distinction form the prior art method" (p. 4, l. 1-3)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, (Fed. Cir. 1987).

The standard for anticipation under section 102 is one of strict identity. An anticipation rejection requires a showing that each limitation of a claim be found in a single reference, *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.,* 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). Further, an anticipatory reference must be enabling, see *Akzo N.V. v. United States Int'l Trade Comm'n* 808 F.2d 1471, 1479, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986), *cert denied*, 482 U.S. 909 (1987), so as to place one of ordinary skill in possession of the claimed invention. To anticipate a claim, a prior art reference must disclose every feature of the claimed invention, either explicitly or inherently. *Glaxo v. Novopharm, Ltd.* 334 U.S. P.Q.2d 1565 (Fed. Cir. 1995).

Claim 1 as previously amended recited the step of "using said result to evaluate said cell's metastatic propensity, wherein metastatic propensity is the propensity of a cell of a given tumor to spread from the tumor to other locations." The Applicants maintain that, contrary to the Examiner's assertions, this step does not "simply express the intended result of a process step", but rather is a bona fide active step of the method, wherein the skilled artisan considers the data and makes a determination as to whether a cell has the propensity to be metastatic or not. Furthermore, because Ricci et al. does not teach using a result of an assay to evaluate a cell's metastatic propensity, Ricci et al. does not anticipate the pending claims. However, in an effort to expedite prosecution and without acquiescing to the correctness of the rejection, the Applicants have amended Claims 1, 14 and 82, upon which the remaining claims depend, to

recite the step of "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." In addition, the Applicants have amended these claims to recite the limitations of Claim 12, namely that the cell being assayed is a lung cancer cell.

The Applicants submit that Ricci et al. also does not anticipate the claims as amended because Ricci et al. does not disclose "comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Ricci et al. teaches assaying for the presence and distribution of NTs and NT receptors in lung malignancies and correlations between such expression and proliferation activity of the tumor cells. (p. 439, col. 2, para. 3). However, Ricci et al. does not teach comparing the result of an assay for the presence of an NT receptor, much less any protein, to a reference data set that is prognostic of metastatic potential, or making an evaluation of the cell's metastatic propensity based upon such a comparison. Ricci et al. is silent on metastasis and the art of determining a cell's metastatic propensity. Accordingly, Ricci et al. does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Thus, Ricci et al. does not anticipate the pending claims. Reconsideration and withdrawal of the rejection is requested.

II. Claims 1-4, 6-11, 13-16 and 81-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Horne et al./ U.S. Patent Application Publication number US 2002/0142981 A1.

In making this rejection, the Examiner asserts that "the publication discloses assaying protein markers for monitoring disease progression, such as the development of liver cancer. The relative amounts of proteins of nucleus associated ribbon-like structure proteins leukotriene B4 12-hydroxydehydrogenase (LTB4DH) and a cyp4 protein, cytochrome P450 were assayed." (p. 5, l. 3-9) In addition, the Examiner asserts that "Applicants' claims recite a step of "using" and newly cited wherein clause, which are not given patentable weight because it simply expresses the intended result of the process step positively recited in the 'assaying' step, see

MPEP 2111.01 [R-3]." (p. 5, l. 11-14) Further to this point, the Examiner asserts that "'Using said result' does not appear to materially differentiate or impart any distinction form the prior art method" (p. 5, l. 14-16)

As discussed above, Claim 1 as previously amended recited the step of "using said result to evaluate said cell's metastatic propensity, wherein metastatic propensity is the propensity of a cell of a given tumor to spread from the tumor to other locations." The Applicants maintain that, contrary to the Examiner's assertions, this step does not "simply express the intended result of a process step", but rather is a bona fide active step of the method, wherein the skilled artisan considers the data and makes a determination as to whether a cell has the propensity to be metastatic or not. Furthermore, because Horne et al. does not teach using a result of an assay to evaluate a cell's metastatic propensity, Horne et al. does not anticipate the pending claims. However, in an effort to expedite prosecution and without acquiescing to the correctness of the rejection, the Applicants have amended Claims 1, 14 and 82, upon which the remaining claims depend, to recite the step of "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." In addition, the Applicants have amended these claims to recite the limitations of Claim 12, namely that the cell being assayed is a lung cancer cell.

The Applicants submit that Horne et al. does not anticipate the pending claims as newly amended because Horne et al. does not disclose "assaying said lung cancer cell for the presence of at least one target protein associated with cellular locomotion to obtain a result". Horne et al. discloses gene profiles of liver cancer cells. The Examiner has indicated that lung cancer cells (Claim 12) is not anticipated by Horne et al. Accordingly, reconsideration and withdrawal of the rejection of Claim 1 is requested.

Thus, Horne et al. does not anticipate the pending claims. Reconsideration and withdrawal of the rejection is therefore requested.

III. Claims 1-4, 6-16, 82 and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Ring et al./U.S. Patent Application Publication number US 2006/0003391.

In making this rejection, the Examiner asserts that "the publication discloses methods of classifying tumors and assaying lung tumor sample for candidate tumor biomarkers, such as cellular locomotion proteins tri-partite-containing motif 29 (TRIM29) and pregnancy-induced growth inhibitor (OKL38)." (p. 6, l. 5-9). In addition, the Examiner asserts that "Applicants' claims recite a step of "using" and newly cited wherein clause, which are not given patentable weight because it simply expresses the intended result of the process step positively recited in the 'assaying' step, see MPEP 2111.01 [R-3]." (p. 6, l. 15-18) Further to this point, the Examiner asserts that "'Using said result' does not appear to materially differentiate or impart any distinction form the prior art method" (p. 6, l. 18-20)

As discussed above, Claim 1 as previously amended recited the step of "using said result to evaluate said cell's metastatic propensity, wherein metastatic propensity is the propensity of a cell of a given tumor to spread from the tumor to other locations." The Applicants maintain that, contrary to the Examiner's assertions, this step does not "simply express the intended result of a process step", but rather is a bona fide active step of the method, wherein the skilled artisan considers the data and makes a determination as to whether a cell has the propensity to be metastatic or not. Furthermore, because Ring et al. does not teach using a result of an assay to evaluate a cell's metastatic propensity, Ring et al. does not anticipate the pending claims. However, in an effort to expedite prosecution and without acquiescing to the correctness of the rejection, the Applicants have amended Claims 1, 14 and 82, upon which the remaining claims depend, to recite the step of "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." In addition, the Applicants have amended these claims to recite the limitations of Claim 12, namely that the cell being assayed is a lung cancer cell.

The Applicants submit that Ring et al. does not anticipate the pending claims because Ring et al. does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Ring et al. teaches panels of markers for classifying tumors (Examples 2-6, para. [0115]-[0131]), wherein the classification is prognostic of recurrence of disease. However, nowhere in Ring et al. does Ring et al. disclose comparing

a result of an assay for the presence of a protein to a reference data set that is prognostic of metastatic propensity, or making an evaluation of a cell's metastatic propensity based upon such a comparison result. Accordingly, Ring et al. does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Thus, Ring et al. does not anticipate the pending claims. Reconsideration and withdrawal of the rejection is requested.

IV. Claims 1-4, 6-16, 82 and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Clarke et al./U.S. Patent Application Publication number US 2006/0019256 A1.

In making this rejection, the Examiner asserts that "the publication discloses assaying solid tumor cancer protein markers in samples of tissue from subjects . . . . The lung cancer types are small-cell lung, non-small cell lung cancer, adenocarcinoma of the lung, and squamous carcinoma of the lung. The following cellular locomotion proteins were assayed TRIM29 (page 12, line 9), LTB4DH and C20orf139 (page 19)." (p. 7, l. 13-20)

As discussed above, Claim 1 as previously amended recited the step of "using said result to evaluate said cell's metastatic propensity, wherein metastatic propensity is the propensity of a cell of a given tumor to spread from the tumor to other locations." The Applicants maintain that this step is a bona fide active step of the method, wherein the skilled artisan considers the data and makes a determination as to whether a cell has the propensity to be metastatic or not. Furthermore, because Clarke et al. does not teach using a result of an assay to evaluate a cell's metastatic propensity, Clarke et al. does not anticipate the pending claims. However, in an effort to expedite prosecution and without acquiescing to the correctness of the rejection, the Applicants have amended Claims 1, 14 and 82, upon which the remaining claims depend, to recite the step of "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." In addition, the Applicants have amended these claims to recite the limitations of Claim 12, namely that the cell being assayed is a lung cancer cell.

The Applicants submit that Clarke et al. does not anticipate the pending claims because Clarke et al. does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Clarke et al. discloses assaying the gene expression levels in two cell populations and comparing them to one another for the purpose of identifying stem cell cancer cells. However, nowhere in Clarke et al. does Clarke et al. describe any of the samples assayed therein as "having a metastatic propensity" or even simply as "metastatic". For example, Clarke et al. does not distinguish the samples used to generate any of the data in thier tables as being representative of metastatic or non-metastatic tissue. Accordingly, Clarke does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result."

Thus, Clarke et al. does not anticipate the pending claims. Reconsideration and withdrawal of the rejection is requested.

REJECTIONS UNDER §103(A)

I. Claims 1-16 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. (Am. J. Respir. Cell. Mol. Biol. 25:439-446, 2001) and further in view of Horne et al./ U.S. patent Application Publication number US 2002/0142981 A1, Ring et al./U.S. Patent Application Publication number US 2006/0003391, and Clarke/U.S. Patent Application Publication number US 2006/0019256 A1.

In order to meet its burden in establishing a rejection under 35 U.S.C. §103, the Office must first demonstrate that a prior art reference, or references when combined, teach or suggest all claim elements. S*ee, e.g., KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007); *Pharmastem Therapeutics v. Viacell et al.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); MPEP § 2143(A)(1). In addition to demonstrating that all elements were known in the prior art, the Office must also articulate a reason for combining the elements. See, *e.g., KSR* at 1741; *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 243 Fed. Appx. 592, 595-596 (Fed. Cir. 2007) citing *KSR*. Further, the Supreme Court in *KSR* also stated that "a court *must* ask whether the improvement is more than the predictable use of prior art elements according to their

established functions." *KSR* at 1740; emphasis added . As such, in addition to showing that all elements of a claim were known in the prior art and that one of ordinary skill in the art had a reason to combine them, the Office must also provide evidence that the combination would be a predicted success.

In making this rejection, the Examiner asserts that "Ricci still reads on Applicants' claimed invention. Ricci et al. does not teach assaying nucleus-associated ribbon-like structure proteins, LTB4DH and a cyp4 protein, cytochrome P450." (p. 8, l. 23-25) The Examiner then asserts that "the publication '2981, now referenced s Horne et al. teaches assaying markers LTB4DH and cytochrome P450 for monitoring disease progression such as the development of liver cancer." (p. 9, l. 1-4) The Examiner further asserts that "Publication '3391 [Ring et al.] teaches methods classifying tumors and assaying lung tumor sample for candidate tumor biomarkers, as well cellular locomotion proteins TRIM29, OKL38." (p. 9, l. 5-8) Finally, the Examiner asserts that "Publication '19256 [Clarke et al.] teaches the following cellular locomotion proteins were assayed TRIM29, LTB4DH and C20orf139." (p. 9, l. 8-10)

Newly amended Claims 1, 14 and 82, upon which the remaining claims depend, recite "assaying said lung cancer cell for the presence of at least one target protein associated with cellular locomotion to obtain a result; comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claim 14

making a prognosis of said subject] based upon said comparison result."

The Applicants submit that Ricci et al. does not teach "comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Ricci et al. teaches assaying for the presence and distribution of NTs and NT receptors in lung malignancies and correlations between such expression and the proliferation activity of tumor cells. (p. 439, col. 2, para. 3). However, Ricci et al. does not teach comparing the result of an assay for the presence of an NT receptor, much less any protein, to a reference data set that is prognostic of metastatic potential, or making an evaluation of the cell's metastatic propensity based upon such a comparison. Ricci et al. is silent on metastasis and the art of determining a cell's metastatic propensity. Accordingly, Ricci et al. does not teach or suggest "comparing said result [of said

assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result."

The Applicants submit that Horne et al. does not remedy the deficiencies of Ricci et al. Horne et al. was provided for teaching markers LTB4DH and cytochrome P450. However, Horne et al. teaches liver cancer, not lung cancer, and it is well understood in the art that cancers arising from different tissues have very different gene profiles. Accordingly, one of ordinary skill in the art would not be able to extrapolate from one cancer to another with any expectation of success. Thus, Horne et al. does not teach or suggest that the markers LTB4DH and a cyp4F protein may be assayed so as to provide an evaluation of metastatic propensity of lung cancer cells.

The Applicants submit that Ring et al. also does not remedy the deficiencies of Ricci et al. Ring et al. was merely provided as teaching markers TRIM29 and OKL38. However, as discussed above, Ricci et al. does not teach "comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Ring et al. does not remedy this deficiency. Ring et al. teaches panels of markers for classifying tumors (Examples 2-6, para. [0115]-[0131]), wherein the classification is prognostic of recurrence of disease. However, nowhere in Ring et al. does Ring et al. disclose comparing a result of an assay for the presence of a protein to a reference data set that is prognostic of metastatic propensity, or making an evaluation of a cell's metastatic propensity based upon such a comparison result. Accordingly, Ring et al. does not teach or suggest "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Thus, Ring et al. does not remedy the deficiencies of Ricci et al.

The Applicants submit that Clarke et al. also does not remedy the deficiencies of Ricci et al. Clarke et al. was provided for teaching TRIM29, LTB4DH and C20orf139. However, as discussed above, Ricci et al. does not teach "comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation

of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Clarke et al. does not remedy this deficiency. Clarke et al. teaches assaying the gene expression levels in two cell populations and comparing them to one another for the purpose of identifying stem cell cancer cells. However, nowhere in Clarke et al. does Clarke et al. describe any data set therein as "having a metastatic propensity" or even simply as "metastatic". For example, Clarke et al. does not distinguish the samples used to generate any of the data in their tables as being representative of metastatic or non-metastatic tissue. Accordingly, Clarke does not disclose "comparing said result [of said assay step] to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result." Thus, Clarke et al. also does not remedy the deficiencies of Ricci et al.

Thus, Ricci et al. in view of Horne et al. (US 2002/0142981 A1), Ring et al. (US 2006/0003391), and Clarke et al. (US 2006/0019256 A1) does not render Claims 1-16 and 81-83 obvious. Reconsideration and withdrawal of the rejection is requested.

II. Claims 1-16 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horne et al./U.S. Patent Application Publication number US 2002/0142981 A1, and further in view of Ricci et al. (Am. J. Respir. Cell. Mol. Biol. 25:439-446, 2001) and further in view of Ring et al./U.S. Patent Application Publication number US 2006/0003391 and Clarke/U.S. Patent Application Publication number US 2006/0019256 A1.

In making this rejection, the Examiner asserts that "the publication discloses assaying protein markers for monitoring disease progression, such as the development of liver cancer. The relative amounts of proteins of nucleus associated ribbon-like structure proteins, leukotriene B4 12-hydroxydehydrogenase (LTB4DH) and a cyp4 protein, cytochrome P450 subfamily IVF were assayed. Horne et al. does not teach OLK38, C20orf139, TRIM29 and NTRK2-TrkB." (p. 10, l. 12-19). The Examiner then asserts that "However, Ricci et al. teaches a method of assaying for the presence of NTRK2/TrkB as well as other proteins associated with cellular locomotion in membranes from human bronchioalveolar carcinoma, adenocarcinoma, squamous cell carcinoma and small cell lung cancer using cytoplasmic immunostaining." (p. 10, l. 20 – p. 11, l. 1). Finally, the Examiner further asserts that "Ring teaches methods classifying tumors and assaying lung tumor sample for candidate tumor biomarkers, as well cellular

locomotion proteins TRIM29 and OKL38" (p. 11, l. 3-5). The Examiner further asserts that "Clarke teaches the following cellular lcomotion proteins were assayed: TRIM29, LTB4DH, and C20orf139." (p. 11, l. 6-8)

Newly amended Claims 1, 14 and 82, upon which the remaining claims depend, recite "assaying said lung cancer cell for the presence of at least one target protein associated with cellular locomotion to obtain a result; comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said lung cancer cell's metastatic propensity [or in the case of Claims 14-16, making a prognosis of said subject] based upon said comparison result."

The Applicants submit that Horne et al. does not teach or suggest Claim 1 or its dependents as amended because Horne et al. does not teach "assaying said lung cancer cell for the presence of at least one target protein associated with cellular locomotion to obtain a result". Horne et al. discloses gene profiles of liver cancer cells, but is silent on lung cancer cells. Thus, Horne et al. does not teach or suggest "assaying said lung cancer cell for the presence of at least one target protein associated with cellular locomotion to obtain a result; comparing said result to a reference data set that is prognostic of metastatic propensity to obtain a comparison result; and making an evaluation of said cell's metastatic propensity [or in the case of Claim 14, making a prognosis of said subject] based upon said comparison result."

The Applicants submit that Ricci et al. does not remedy the deficiencies of Horne et al. Ricci was provided for teaching assaying for the presence of NTRK2/TrkB. However, Ricci does not teach or suggest comparing the result of an assay for the presence of an NT receptor, much less any protein, to a reference data set that is prognostic of metastatic propensity, or making an evaluation of the cell's metastatic propensity based upon such a comparison." Ricci et al. teaches assaying for the presence and distribution of NTs and NT receptors in lung malignancies and correlations between such expression and the proliferation activity of tumor cells. (p. 439, col. 2, para. 3). However, Ricci et al. is silent on metastasis and the art of making an evaluation of a cell's metastatic propensity. Accordingly, one of ordinary skill in the art would not be able to predict with any expectation of success that combining the elements of Ricci et al. with those of Horne et al. would provide for making an evaluation on a cell's metastatic propensity. Thus, Ricci et al. does not remedy the deficiencies of Horne et al.

The Applicants submit that Ring et al. also does not remedy the deficiencies of Horne et al. Ring et al. was provided for teaching a method of assaying for the presence of TRIM29 and OKL38. However, Ring et al. does not teach or suggest comparing the result of an assay for the presence of TRIMP29 or OKL38, much less any protein, to a reference data set that is prognostic of metastatic propensity, or making an evaluation of the cell's metastatic propensity based upon such a comparison. Ring et al. teaches panels of markers for classifying tumors (Examples 2-6, para. [0115]-[0131]), wherein the classification is prognostic of recurrence of disease. However, nowhere in Ring et al. does Ring et al. disclose comparing a result of an assay for the presence of a protein to a reference data set that is prognostic of metastatic propensity, or making an evaluation of a cell's metastatic propensity based upon such a comparison result. Accordingly, one of ordinary skill in the art would not be able to predict with any expectation of success that combining the elements of Ring et al. with those of Horne et al. would provide for making an evaluation on a cell's metastatic propensity. Thus, Ring does not remedy the deficiencies of Horne et al.

The Applicants submit that Clarke et al. also does not remedy the deficiencies of Horne et al. Clarke et al. was provided for teaching a method of assaying for the presence of TRIM29, LTB4DH, and C20orf139. However, Clarke et al. does not teach or suggest comparing the result of an assay for the presence of TRIM29, LTB4DH, or C20orf139, much less any protein, to a reference data set that is prognostic of metastatic propensity, or making an evaluation of the cell's metastatic propensity based upon such a comparison. Clarke et al. teaches assaying the gene expression levels in two cell populations and comparing them to one another for the purpose of identifying stem cell cancer cells. However, nowhere in Clarke et al. does Clarke et al. describe any of the samples assayed therein as "having a metastatic propensity" or even simply as "metastatic". For example, Clarke et al. does not distinguish the samples used to generate any of the data in their tables as being representative of metastatic or non-metastatic tissue. Accordingly, one of ordinary skill in the art would not be able to predict with any expectation of success that combining the elements of Clarke et al. with those of Horne et al. would provide for making an evaluation on a cell's metastatic propensity. Thus, Clarke et al. does not remedy the deficiencies of Horne et al.

Thus, Horne et al. (US 2002/0142981 A1) in view of Ricci et al and further in view of Ring et al. (US 2006/0003391) and Clarke et al. (US 2006/0019256 A1) does not render Claims 1-16 and 81-82 obvious. Reconsideration and withdrawal of the rejection is requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-349.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: August 13, 2009

By: /Elizabeth A. Alcamo, Reg. No. 64,133/
Elizabeth A. Alcamo, Ph.D.
Registration No. 64,133

Date: August 13, 2009

By: /Bret E. Field, Reg. No. 37,620/
Bret E. Field
Registration No. 37,620

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

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